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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/754,010	01/03/2001	Mark E. Dillon	E-1950	3438
7590 John F. A. Earley III 86 The Commons At Valley Forge East 1288 Valley Forge Road P.O. Box 750 Valley Forge, PA 19482-0750			EXAMINER LANDAU, SHARMILA GOLLAMUDI	
			ART UNIT 1611	PAPER NUMBER
			MAIL DATE 03/18/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/754,010

Applicant(s)

DILLON, MARK E.

Examiner

Sharmila Gollamudi Landau

Art Unit

1611

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-54 is/are pending in the application.
- 4a) Of the above claim(s) 46-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Receipt of Amendments/Remarks filed 12/14/07 is acknowledged. Claims 34-45 are directed to the elected invention. Claims 46-54 are withdrawn as being directed to the non-elected invention. Claims 1-33 stand cancelled.

Election/Restrictions

Claims 34-45 are directed to the constructively elected invention. However, applicant traverses the restriction requirement of claims 50-54. The traversal is on the ground(s) that "in order for the claimed product to be used as a transdermal product to deliver drugs, the method of use as claimed by the Applicant would be used."

This is not found persuasive because:

Claim 50 is directed to: A method of using a dual-purpose wound dressing capable of providing disparate wound healing characteristics to a wound, comprising the steps of providing a multilayered composite structure, the multilayered composite structure having a first wound contacting side having an outer wound contacting surface that has wound healing characteristics and a second wound contacting side having an outer wound contacting surface that has wound healing characteristics different from the wound healing characteristics of the outer surface of the first side of the composite structure, the multilayered structure including a first layer forming the first wound contacting side of the composite structure, the first layer being a membrane layer, and a second layer forming the second wound contacting side of the composite structure, the second layer being a foam layer, choosing the outer wound contacting surface desired to be applied to the wound to provide the wound healing characteristics of the chosen outer wound contacting surface to the wound, and **applying the dressing to the wound**

with the chosen outer wound contacting surface contacting the wound to provide the wound healing characteristics of the chosen outer wound contacting surface to the wound.

Therefore, although the preamble is directed to a "method of using" without defining the use, the method steps are directed to using the dual-purpose wound dressing for wounds specifically. Thus, the reason for restriction in the Office Action of 6/11/07 is proper. The examiner points out that although the treatment populations *may be* overlapping, they are not necessarily the same. For instance, a patient utilizing the dressing for a wound will not necessarily require treatment with a drug. Similarly, a patient utilizing the dressing for hormone replacement will not necessarily utilize the dressing for its wound healing characteristics.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 34-36 and 45 are rejected under 35 U.S.C. 102(e) as being anticipated by Lindqvist et al (6,051,747).

Lindqvist et al disclose a wound dressing a gel layer (3), which is reticulated into a polyurethane foam layer (2) with open cells (fenestrations) and a thickness of 1-10mm (1000microns to 10,000 microns), and a liquid impervious layer made of a polyurethane film (5). See Figures. The gel layer 3 does not close, but only covers, a part of the walls in an end portion

of the pores of the foam material that face the wound, excess wound fluid can be drawn into the foam material 2 and absorbed thereby. The polyurethane film is glued to the foam layer. See column 5, lines 63-65. The polyurethane film has high vapor permeability and a thickness of 0.025 mm (25 microns). See column 5, lines 63-65. Note that the polyurethane film in this embodiment read on the instant membrane layer since “membrane” is defined as “a thin sheet of natural or synthetic material”. Note also in this embodiment the glue reads on the adhesive layer since the glue acts to bond the foam and the film.

With regard to lines 4-9 of independent claim 34, Lindqvist discloses a wound dressing that is multi-layered wherein the two layers are different, i.e. made of different material. Thus, the dressing necessarily have different wound healing properties and the would dressing is capable of meeting the intended use recited in lines 4-9. The instant invention and the prior art are not structurally distinguishable and thus the prior art is capable of performing the recited intended use.

Response to Arguments

Applicant argues that although Lindqvist discloses a gel layer and an absorbent foam, Lindqvist does not suggest or discloses a dual purpose wound dressing with disparate would healing characteristic. Applicant argues that Lindqvist disclose that the foam layer is sandwiched between two layers, i.e. the gel layer and the liquid impervious layer. Thus, applicant argues that the instant invention is structurally distinguishable from the prior art since the foam layer is not directly contacting the wound.

Applicant's arguments filed 12/14/07 have been fully considered but they are not persuasive. The instant invention is directed to a product and not the method of use; thus the

determination of patentability is based on the product itself. The instant product is directed to a multilayered structure that comprises one wound contacting surface having "healing characteristics" and a second wound contacting surface having different "healing characteristics" wherein the first layer is a membrane layer and the second layer "being a foam layer." The instant claims have open-ended claim language. Thus, the instant claims language "comprising" does not exclude additional layers such as Lindqvist's gel layer. Note MPEP 2111.03. Thus, in a first interpretation, the combination of the foam and gel can read on the "second layer" since it contains a layer of foam and does not exclude the gel. In the second interpretation, "the second wound contacting side" is construed to be formed of gel and foam and Lindqvist's foam is "the second layer" of this "second wound contacting side" since it forms part of the "second wound contacting side". Lastly, the layers will necessarily have different healing characteristics since Lindqvist discloses two layers made of two different material. Therefore, Lindqvist's structure and the instant invention *as claimed* are not structurally distinguishable and the prior art's wound dressing is capable of performing the recited intended use.

Therefore, the instant claims are anticipated.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 34, 36, 40, and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Hofeditz et al (4,552,138).

Hofeditz et al disclose a dressing material comprising at least one layer of hydrophilic, transparent polymeric gel (see column 2, lines 44-45) and a carrier material. Example 5 discloses the gel layer laminated to an open-pore (fenestrations) polyurethane foam. Hofeditz discloses the additional use of dyes and pigments. See claim 13 and examples.

It should be noted that membrane is defined as a “thin, soft pliable sheet or layer”; thus Hofeditz polymeric gel layer reads on “membrane layer”.

With regard to lines 4-9 of independent claim 34, Hofeditz discloses a wound dressing that is multi-layered wherein the two layers are different, i.e. made of different material. Thus, the dressing necessarily have different wound healing properties and the would dressing is capable of meeting the intended use recited in lines 4-9. The instant invention and the prior art are not structurally distinguishable and thus the prior art is capable of performing the recited intended use.

Response to Arguments

Applicant argues although Hofeditz has a gel layer having an outer wound-contacting surface, Hofeditz, in contrast to Applicant's invention, has a foam layer as an intermediate or cover layer. Applicant argues that Hofeditz does not disclose a foam layer having an outer wound contacting surface having wound healing characteristics, as called for by Applicant's claim 34.

Applicant's arguments filed 12/14/07 have been fully considered but they are not persuasive. The instant invention is directed to a product and not the method of use; thus the determination of patentability is based on the product itself. The instant invention is directed to a wound dressing comprising 1) a membrane layer and 2) a foam layer. The prior art discloses a 1) a gel layer that reads on the membrane layer since a membrane is defined as a “thin, soft pliable sheet or layer” and 2) a polyurethane foam layer. As acknowledged by applicant, the foam is a cover layer and thus has an outer wound contacting surface. Further, the layers will necessarily have different healing characteristics since Hofeditz discloses two layers made of two different

material. Thus, the prior art's wound dressing is capable of performing the recited intended use since Hofeditz's structure and the instant invention as claimed are not structurally distinguishable. Meaning the wound dressing is capable of being used upside down. Again, the examiner points out that the claimed intended use of the dressing, i.e. using in an upside down manner, does not impart a structural difference since the prior art may also be turned upside down since it has a foam layer and a membrane layer.

Therefore, the instant claims are anticipated.

Claims 34-36, 38, 42-43, and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Freeman (5,681,579).

Freeman discloses a polymeric support wound dressing. See abstract. Figure 1 discloses the occlusive layer (11) (second layer) bonded by adhesives (13) means to a hydrocolloid containing polymeric layer (12) (first layer).



The occlusive layer 11 has an upper or outer surface 14, which is open to the atmosphere and an inner surface 13, which is the side toward the skin. The occlusive layer is preferably polyurethane foam. See column 4, lines 30-31. The adhesive layer may for example extend across the entire under surface 13 of the occlusive layer or only a portion of it. The polymeric support layer 12 is any polymeric material useful in medical settings and is in the form of a web, net, perforated film or perforated layer. The polymeric support layer 12 contains a hydrocolloid either blended with the polymeric material. When the hydrocolloid is blended with the polymeric

material it is preferred that the two materials be extruded together to form a film. See column 5, lines 1-30. It should be noted that a membrane is defined as a “thin, soft pliable sheet or layer”; thus Freeman’s polymeric support reads on instantly claimed “membrane layer”. The polymeric support layer is 0.5-3 mils (35 microns to 76 microns). See column 4, lines 5-8. The adhesive layer is made of various substances including silicone rubber. See column 6, line 31.

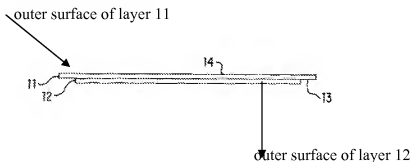
Dressing A discloses a hydrocolloid centered on polyurethane foam, which is adhered to a perforated polyurethane perforated film. See column 10, lines 20-45.

With regard to lines 4-9 of independent claim 34, Freeman discloses a wound dressing that is multi-layered wherein the two layers are different, i.e. made of different material. Thus, the dressing necessarily have different wound healing properties and the would dressing is capable of meeting the intended use recited in lines 4-9. The instant invention and the prior art are not structurally distinguishable and thus the prior art is capable of performing the recited intended use. Moreover, a portion of layer 11, the foam, along with layer 12, contacts the skin surface as disclosed by Freeman on column 4, lines 13-15.

Response to Arguments

Applicant argues that the instant invention is directed to novel wound dressing that has two wound contacting layers each with its own wound healing characteristics. Applicant argues that Freeman does not have both a membrane layer with an outer wound contacting surface and a second wound contacting side with an outer wound contacting surface. Applicant argues that the occlusive layer does not contact the wound surface since it has an adhesive layer that covers its overhanging portion.

Applicant's arguments filed 12/14/07 have been fully considered but they are not persuasive. The instant invention is directed to a product and not the method of use; thus the determination of patentability is based on the product itself. The instant invention is directed to a wound dressing comprising 1) a membrane layer, 2) an adhesive layer, and 3) a foam layer. The prior art discloses a 1) polymeric membrane layer (12), 2) an adhesive layer (13), and 3) a polyurethane foam layer (11).



It is noted that dependent claim 35 is directed to an adhesive layer adjoining both the first and second layer. Thus, applicant's argument regarding the adhesive layer is perplexing. Each respective layer has an outer surface. Further, since the prior art discloses two layers made of two different material, i.e. a polymeric membrane layer and a foam layer, Freeman's layers will inherently have different healing characteristics. Thus, since Freeman's structure and the instant invention as claimed are not structurally distinguishable, the prior art's wound dressing is capable of performing the recited intended use. The examiner further points out that the instant disclosure states that using the instant invention "upside down" provides the dual purpose; thus Freeman's dressing is also capable of being turned "upside down" to provide the dual function.

Applicant discloses on page 5, lines 22-25:

"By applying the dressing to the wound site with the IPN surface against the wound surface...."

On page 6, lines 4-12, applicant discloses:

"I have discovered that the dressing...is also useful when used up-side down with the foam layer against the wound instead of the IPN layer."

The examiner notes that depending on which side one desires to contact the wound, the prior art, which is structurally indistinguishable, can also be flipped accordingly.

In an alternative interpretation, it is pointed out that a portion of layer 11 (foam occlusive layer) contacts the skin. The examiner points out that Freeman discloses that the adhesive layer may be applied to only a portion of layer 11. Therefore, the overhanging portion of layer 11 as seen in Figure 1, does in fact, contact the wound as disclosed by Freeman on column 4, lines 13-15.

Therefore, the instant claims are anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 37, 39-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindqvist et al (6,015,747) in view of Lorenz et al (5,258,421) and as evidenced by US 4832009.

The disclosure of Lindqvist has been set forth above.

Lindqvist does not teach the use of instant silicone-polytetrafluoroethylene IPN membrane layer. Further, the addition of a pigment is not taught.

Lorenz et al teaches a hydrophilic gel dressing (Note abstract). The dressing is made of a tacky gel of polyurethane and poly (N-vinyl lactam) on a substrate. Lorenz teaches coating the gel layer on a backing substrate. The backing substrate provides liquid barrier properties and may be a polymer film such as polyurethane film or silicone-polytetrafluoroethylene IPN membrane film. Lorenz teaches silicone-polytetrafluoroethylene has particular utility in wound dressing because it keeps moisture in and excess exudate is absorbed to promote healing. See column 5, lines 50-68. When the backing substrate is of the instant silicone-polytetrafluoroethylene, the structure is also useful as a burn blanket. See 5, lines 30-33 and column 6, lines 28-30. Additionally, Lorenz teaches the use of various conventional additives such as pigments and dyes in the gels. See column 4, lines 49-55. It should be noted that IPN is implicitly translucent evidenced by US '009.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Lindqvist et al and Lorenz et al and replace Lindqvist's polyurethane polymer film with the instant silicone-polytetrafluoroethylene IPN polymer film. One would have been motivated to do so since Lorenz teaches that both polyurethane films and the instant film have Liquid barrier properties; however the instant IPN polymer film provides

certain advantages for wound and burn dressing by keeping the moisture in, preventing bacteria from entering the wound and absorbing the excess exudates, thereby promoting healing. Therefore, a skilled artisan would have been motivated to utilize the instant polymer film (IPN) in Lindqvist's wound dressing over Lindqvist's polyurethane film for the advantages taught by Lorenz, i.e. if one desired to provide a structure that also promoted healing by preventing re-infection, i.e. by preventing bacteria from entering the wound site. A skilled artisan would have reasonably expected success and similar results since Lorenz teaches both Lindqvist's polyurethane film and instant silicone-polytetrafluoroethylene IPN function in a similar manner, i.e. functional equivalents (both are liquid impervious layers that are utilized in wound dressing).

With regard to claim 40, it would have been obvious to add a pigment to Lindqvist's gel if one desired for an article with a gel layer with a distinct layer. It should be noted that the instantly claimed aesthetic design change does not impart patentable significance with regard to the mechanism in which the wound article functions.

With regard to claim 41, it is noted that polymeric film layers are implicitly translucent unless a pigment is added. Further, it should be noted that US '009 substantiates the examiner's position that the silicone-polytetrafluoroethylene IPN are transparent. Note column 1, lines 55-60 of US '009. Thus, thus reads on "substantially transparent". Further, polyurethane foams are implicitly opaque. With regard to the addition of pigment to the adhesive layer, it is considered prima facie obvious to add a pigment to any layer to distinguish each layer. It should be noted that the instantly claimed aesthetic design change does not impart patentable significance with regard to the mechanism in which the wound article functions. Thus, if pigment is added to the adhesive layer, it will implicitly be seen through the first layer.

With regard to claim 42, pores (fenestrations) are a property of silicone-polytetrafluoroethylene IPN films. US '009 substantiates this. Note column 1, lines 45-60 of US '009.

Response to Arguments

Applicant argues that Lindqvist does not teach using the wound dressing in the instant manner; i.e. an upside down manner. Applicant argues that this use is gleaned from applicant. Applicant argues that Lorenz does not teach a dual surface wound dressing and the IPN layer is merely provided to protect the gel and not contact the skin.

Applicant's arguments filed 12/17/07 have been fully considered but they are not persuasive. The arguments pertaining to Lindqvist teaching a gel layer on the foam layer have been addressed above and incorporated herein. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In instant case, applicant has not addressed the examiner's motivation to combine the references and has rather analyzed each reference separately. The primary reference is not deficient in the teaching of a two layer wound dressing. Thus, neither Lorenz nor US 4832009 need to teach this. The premise of the instant rejection is that Lorenz provides the motivation to substitute Lindqvist's polyurethane film with the instant IPN film, by teaching both are functional equivalents. Applicant has not provided any arguments or evidence of the unobvious difference. Again, applicant is arguing the intended use of the wound dressing and the examiner points out that intended use is not given patentable weight unless it imparts a structural

difference. In instant case, it does not. Lindqvist teaches a two-layer wound dressing as claimed and thus is capable of performing the intended use. Regarding US 4832009, this reference is only relied upon to substantiate the inherent properties of IPN films.

Applicant argues that the addition of the pigment is not merely a design change but functions as a visual indicator differentiating one side from the other. Applicant argues that none of the reference teach mixing a pigment to the adhesive layer to distinguish one side from the other.

The examiner notes that the addition of the pigment is a structural change. The examiner has not attempted to argue that it does not. The examiner has merely pointed out that adding a pigment to a layer does not change the mechanism of the wound dressing, i.e. providing a non-obvious dressing. It is the examiner's position that adding a pigment to any layer in view of Lorenz's teachings is obvious absent evidence of unexpectedness.

Therefore, the instant claims are rendered obvious over the cited art.

Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lindqvist et al (6,015,747) by itself or in view of Freeman (5,681,579).

The disclosure of Lindqvist has been set forth above. The reference teaches the foam has a thickness of 1-10mm (1000microns to 10,000 microns), and a liquid impervious layer (polyurethane film) has a thickness of 0.025 mm (25 microns).

Lindqvist does not teach the instant thickness of the membrane layer, i.e. 50 microns.

Freeman teaches a polymeric support wound dressing, which comprises an occlusive layer and a support layer. See abstract. Figure 1 discloses the occlusive layer (11) (second layer) is preferably a polyurethane foam bonded by adhesives (adhesive layer) means to a perforated film

(12) (first layer). See also column 4 to column 5 and examples. Dressing A discloses a hydrocolloid centered on a polyurethane foam, which is adhered to a perforated polyurethane perforated film. See column 10, lines 20-45. The polymeric support layer is 0.5-3 mils (35 microns to 76 microns). See column 4, lines 5-8.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance provided by Lindqvist and manipulate the thickness of the liquid impervious layer from 25 microns to 50 microns. One would have been motivated to manipulate the thickness of this layer since the polymeric layer functions to support the foam layer. Thus, depending on factors such as the weight and thickness of the foam layer one would have been motivated to utilize the appropriate thickness to support the foam layer and provide strength to the entire structure.

Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Lindqvist and Freeman and manipulate the thickness of the liquid impervious layer from 25 microns to 50 microns. One would have been motivated to do so since Freeman teaches polyurethane films may be in a thickness of 35-76 microns. Therefore, a skilled artisan would have been motivated to manipulate the thickness of this layer since the polymeric layer functions to support the foam layer. Thus, depending on factors such as the weight and thickness of the foam layer one would have been motivated to utilize the appropriate thickness to support the foam layer and provide strength to the entire structure.

Response to Arguments

Applicant argues that Lindqvist teaches a foam layer that is sandwiched between the outer two layers.

Applicant's arguments filed 12/14/07 have been fully considered but they are not persuasive. The merits of Lindqvist has been addressed above and incorporated herein. Therefore, the instant claims are rendered obvious over the cited art.

Claims 37, 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman (5,681,579) in view of Lorenz et al (5,258,421) and as evidenced by US 4832009.

The disclosure of Freeman has been set forth above.

Freeman does not teach the use of instant silicone-polytetrafluoroethylene IPN membrane layer or a pigment.

Lorenz et al teaches a hydrophilic gel dressing (Note abstract). The dressing is made of a tacky gel of polyurethane and poly (N-vinyl lactam) on a substrate. Lorenz teaches coating the gel layer on a backing substrate that provides liquid barrier properties and may be a polymer film such as polyurethane. The polymer film may also be silicone-polytetrafluoroethylene IPN membrane. Lorenz teaches silicone-polytetrafluoroethylene has particular utility in wound dressing because it keeps moisture in and excess exudate is absorbed to promote healing. See column 5, lines 50-68. When the backing substrate is of the instant silicone-polytetrafluoroethylene, the structure is also useful as a burn blanket. See 5, lines 30-33 and column 6, lines 28-30. Additionally, the backing substrate may be covered by a silicone-coated release-liner. Additionally, Lorenz teaches the use of various conventional additives such as

pigments and dyes in the gels. See column 4, lines 49-55. It should be noted that IPN is implicitly translucent.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Freeman et al and Lorenz et al and replace Freeman's polyurethane polymer film with the instant silicone-polytetrafluoroethylene IPN polymer film. One would have been motivated to do so since Lorenz teaches that both polyurethane films and the instant film have Liquid barrier properties; however the instant IPN polymer film provides certain advantages for wound and burn dressing by keeping the moisture in, preventing bacteria from entering the wound and absorbing the excess exudates, thereby promoting healing. Therefore, a skilled artisan would have been motivated to utilize the instant polymer film (IPN) in the wound dressing over Freeman's polyurethane film for the advantages taught by Lorenz, i.e. if one desired to provide a structure that also promoted healing by preventing re-infection, i.e. by preventing bacteria from entering the wound site.

With regard to claim 40, it would have been obvious to add a pigment to the gel if one desired for an article with a gel layer with a distinct layer. It should be noted that the instantly claimed aesthetic design change does not impart patentable significance with regard to the mechanism in which the wound article functions.

With regard to claim 41, it is noted that polymeric film layers are implicitly translucent unless a pigment is added. Further, it should be noted that US '009 substantiates the examiner's position that the silicone-polytetrafluoroethylene IPN are transparent. Note column 1, lines 55-60 of US '009. Thus, thus reads on "substantially transparent". Further, polyurethane foams are implicitly opaque. With regard to the addition of pigment to the adhesive layer, it is considered

prima facie obvious to add a pigment to any layer to distinguish each layer. It should be noted that the instantly claimed aesthetic design change does not impart patentable significance with regard to the mechanism in which the wound article functions. Thus, if pigment is added to the adhesive layer, it will implicitly be seen through the first layer.

Response to Arguments

Applicant argues the combination of Freeman and Lorenz only teach a single-sided dressing and cannot be used in the instant manner.

Applicant's arguments filed 12/14/07 have been fully considered but they are not persuasive. The merits of Freeman have been discussed above under the anticipation rejection and thus the examiner's response to applicant's arguments is incorporated herein. Therefore, the instant claims are rendered obvious over the cited art.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila Gollamudi Landau whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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